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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,925	01/09/2001	Christian Quellet	12846/121488	6779

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,925	QUELLET ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendment filed on April 18, 2004. Rejection made under 35 U.S.C. § 103 (a) over Tsuei et al. in (US 5589194) view of Carr et al. (US 5183690) and Lee et al. (EP 0480729 A1) as indicated in the previous Office action dated November 19, 2003 is withdrawn in view of the claim amendment and new rejection is made to address the new limitation. Rejection made under § 103 (a) over Tsui et al., Carr et al., and Lee et al., and further in view of Bilbrey (US 5290547) as indicated in the same Office action is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 2-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei et al. (US 5589194) ("Tsuei") in view of Carr et al. (US 5183690) ("Carr") and Lee et al. (EP 0480729 A1) ("Lee").

Tsuei teaches microcapsules having water-soluble or insoluble active components dissolved or dispersed, respectively, in solid thermoplastic matrix. See abstract; col. 3, line 21 – col. 4, line 67. See also Example 7, which teaches microcapsules containing beta-carotene in vegetable oil. The reference also teaches that the amount of the active components and size of the microcapsule can be controlled by the prior art process. See col. 3, lines 27 – 39. The reference also teaches the method of making microcapsules via extrusion process. See col. 3, line 64- col. 4, line 7. See instant claims 11-13.

Tsuei fails to specifically teach the size of the microcapsules. The reference also fails to teach starch matrix.

Carr teaches encapsulated biologically active agents in a starch matrix. See abstract. The reference teaches that it is well known in the art to employ natural or modified starch for water-insoluble materials. See col. 1, lines 36-42; col. 3, lines 15 – 22; col. 5, lines 3 – 28. Carr also teaches that core materials "dissolved, emulsified, or otherwise dispersed in solvents or carriers" are encapsulated. See col. 3, lines 36-43, suggesting that liquid actives in emulsion form are obvious. The biological actives suitable for the invention include flavor composition, odor composition, vitamin, and bactericide. See col. 3, lines 23-36. See instant claims 6-9.

Carr fails to teach the size of the microcapsule as recited by the instant claims.

Lee discloses method of microencapsulating oil droplet containing drugs for oral administration using polysaccharide as a capsule material. See abstract. The reference teaches mixing the drug with liquid oil and producing an oil-in-water emulsion containing the drug-dispersed oil droplets of 1-5 microns. The reference also teaches that the final product is in powdery state. See Example 1. The reference teaches using the drug in the amount of 1-40 % of the liquid oil. See instant claims 4-5. See also p. 3, lines 25 – p. 4, line 24 for the weight amounts of chelating agent, emulsifier, and the capsule material. It is viewed that the "hydrophobic inclusion" limitation is met because the prior art teaches

that the drug is mixed with oil which is then emulsified with water. See p. 3, lines 25 – 31.

While the reference fails to teach the size of the microcapsules per se, given that the size of the droplet is within 1-5 microns, examiner takes the position that the prior art microcapsules are within the obvious range of the claimed limitation, absent evidence to the contrary.

Examiner notes that claims 28 is a product by process claim. It is well known in patent law that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, claim 28 is rejected here because the recited method is not give patentable weight, and the powdery microencapsulated composition meets the limitation of the recited composite material.

For claim 10, it is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teaching, the instant claims define

nothing more than the concomitant use of two biological actives for controlled-release. It would follow that the recited claims define prima facie obvious subject matter.

Given the general teaching of controlling the size of microcapsules by techniques known in the art, as taught in Tsuei, it would have been obvious to one having ordinary skill in the art at the time of the invention to have looked to the prior arts such as Lee and produced the microcapsules having size of 1-5 microns.

2. Claims 38-41are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei, Carr, and Lee as applied to claims 2-37 above, and further in view of Bilbrey (US 5290547).

Tsuei, Carr, and Lee fail to teach using the surfactants and the amount of the components as recited in the instant claims.

Bilbrey teaches odor-masking products comprising coated oil-in-water emulsion droplets of fragrance oil for the use odor masking products. See abstract; col. 1, line 61 – col. 2, line 55. The reference teaches that the size of the droplets is in the range of 2-300 μm. See col. 3, lines 11 – 26. Adding emulsifiers such as sodium lauryl sulphate, sorbitan tristearate, sorbitan trioleate or sorbitan monooleate for surfactants is disclosed in col. 4, lines 54 – 65. The amount of actives, water, surfactant, and additives in microemulsion is disclosed in col. 5, lines 29-41.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composite materials of the combined references by adding the surfactants and components as suggested by Bilbrey, because of the expectation of successfully producing a uniform dispersion of active ingredients in the composite materials.

Response to Arguments

Applicant's arguments filed on April 18, 2004 have been considered but are not persuasive.

Applicants' assertion that Lee teaches oil-in-water emulsion as the final product is incorrect because the emulsion is in fact microencapsulated with a capsule material. See Lee, abstract.

Applicants also argue that the 1-5 microns taught in Lee are size distribution ranges and does not represent an overlap of ranges of the inclusion. The Lee reference teaches that the size of drug-dispersed oil droplet has size of 1-5 microns, which meets the limitation of size of inclusion. As for the size of the microcapsule in as claimed in instant claim 25, Tsuei teaches that that the amount of the active components and size of the microcapsule can be controlled by the prior art process. See col. 3, lines 27 – 39. Thus, the manipulation of the size of microcapsule is obviously within the skill of the art.

While applicants argue that there is no reasonable expectation of success in substituting the Lee polysaccharide with Carr starch matrix, examiner respectfully notes that Lee is cited to show that the claimed droplet size of active ingredient in emulsion form is well known in pharmaceutical microencapsulation

art. The sonification technique used in Lee need not be applied in making Tsuei or Carr inventions.

While applicants assert that the claimed invention is made by a different process not disclosed in Tsuei, Carr and Lee, examiner reiterates that in product-by-process claims, how the product is not made is not given patentable weight. See In re Thorpe.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While applicants assert that Lee and Bibrey references fail to teach all the elements of the claims, examiner respectfully points out that the present rejections are made in view of the collective teachings of the references and based on what one of ordinary skill in the art would have reasonably found obvious at the time of the invention. While applicants argues that "as a whole" consideration requirement is not met, it is not clear what specifically negates the motivation to combine the references.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER